

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

6619 '00 OCT 11 P1:44

Date: October 6, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Office of Generic Drugs and Generic Industry Meeting

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Office of Generic Drugs and Generic Industry Meeting

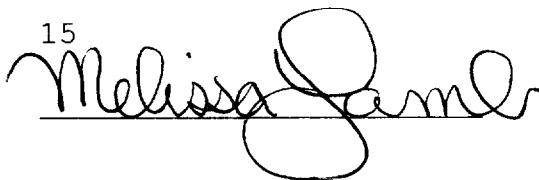
Presented for: Generic Industry Meeting

Date Presented: September 20, 2000

Presented by: Gary Buehler

Number of Pages:

15

A handwritten signature in black ink, appearing to read "Melissa Lamb", is written over a horizontal line.

Attachment

90S-0308

M 689



Office of Generic Drugs and Generic Industry Meeting

**September 20, 2000
Rockville, MD**

**Gary Buehler, Acting Director
Office of Generic Drugs**

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Welcome!

Future Meetings - Questionnaire
Lunch & Breaks

"Thank you"

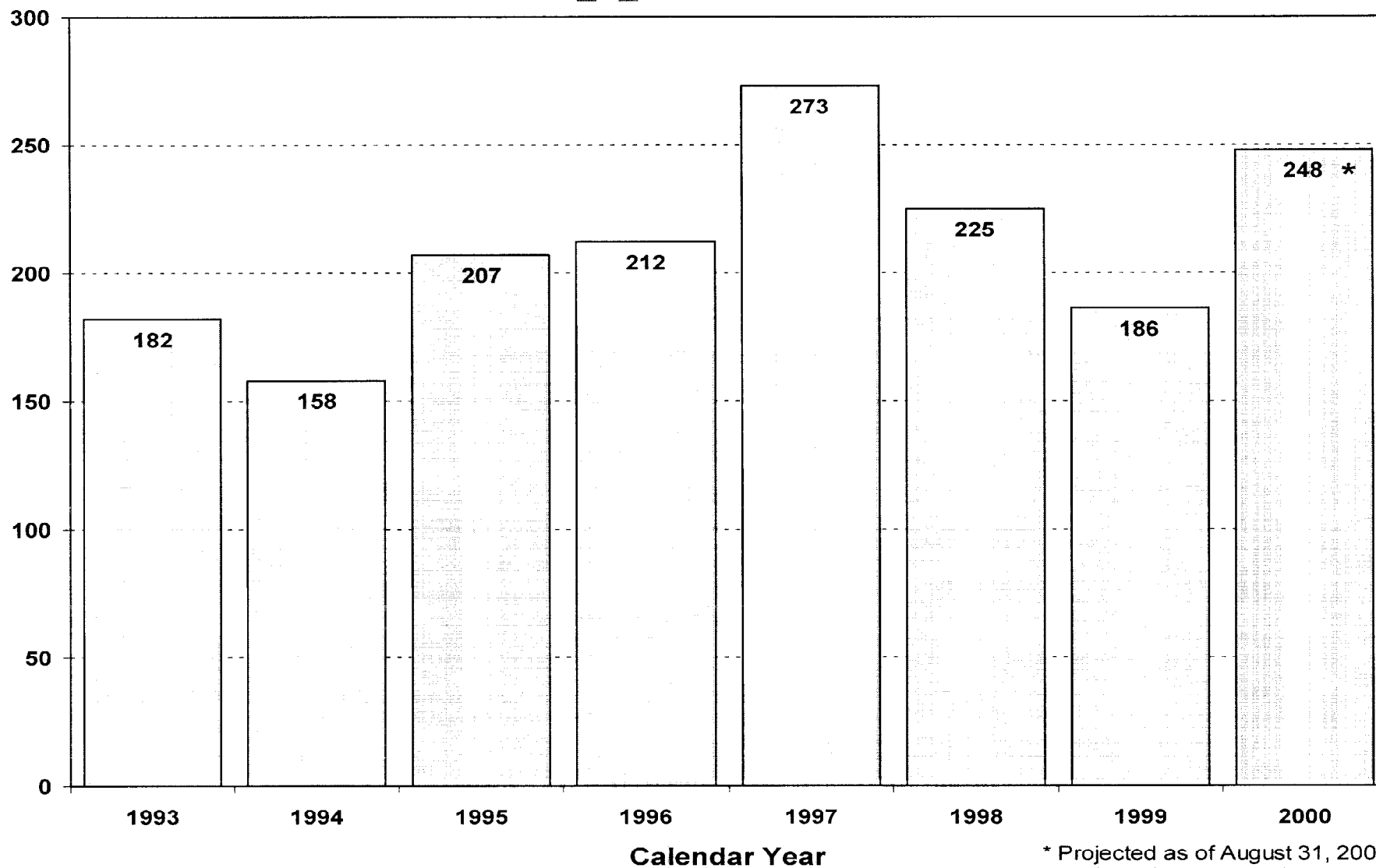
Pat Downs - Registration

Rita Hassall - Program

Patti Littleton - Refreshments



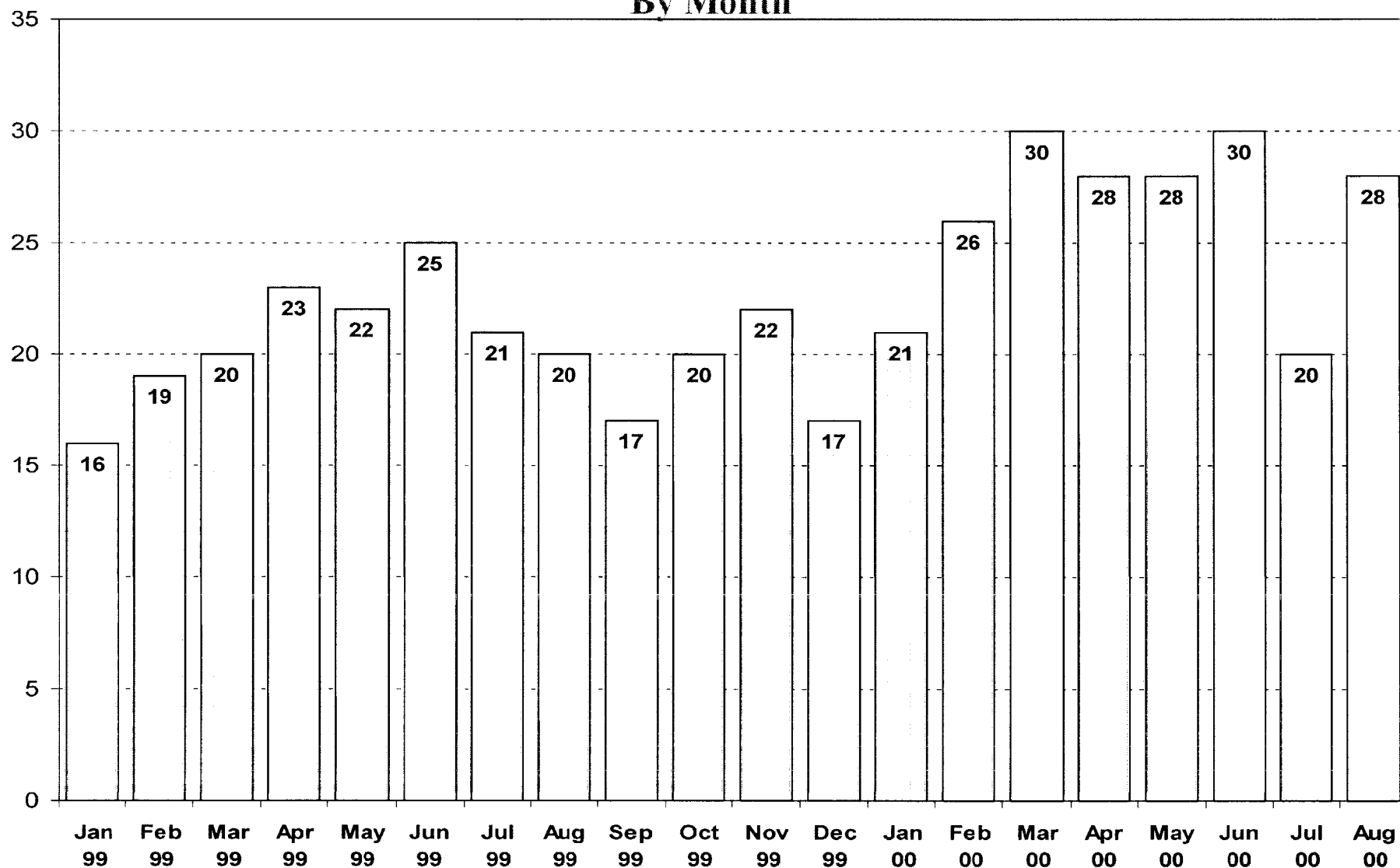
Approvals





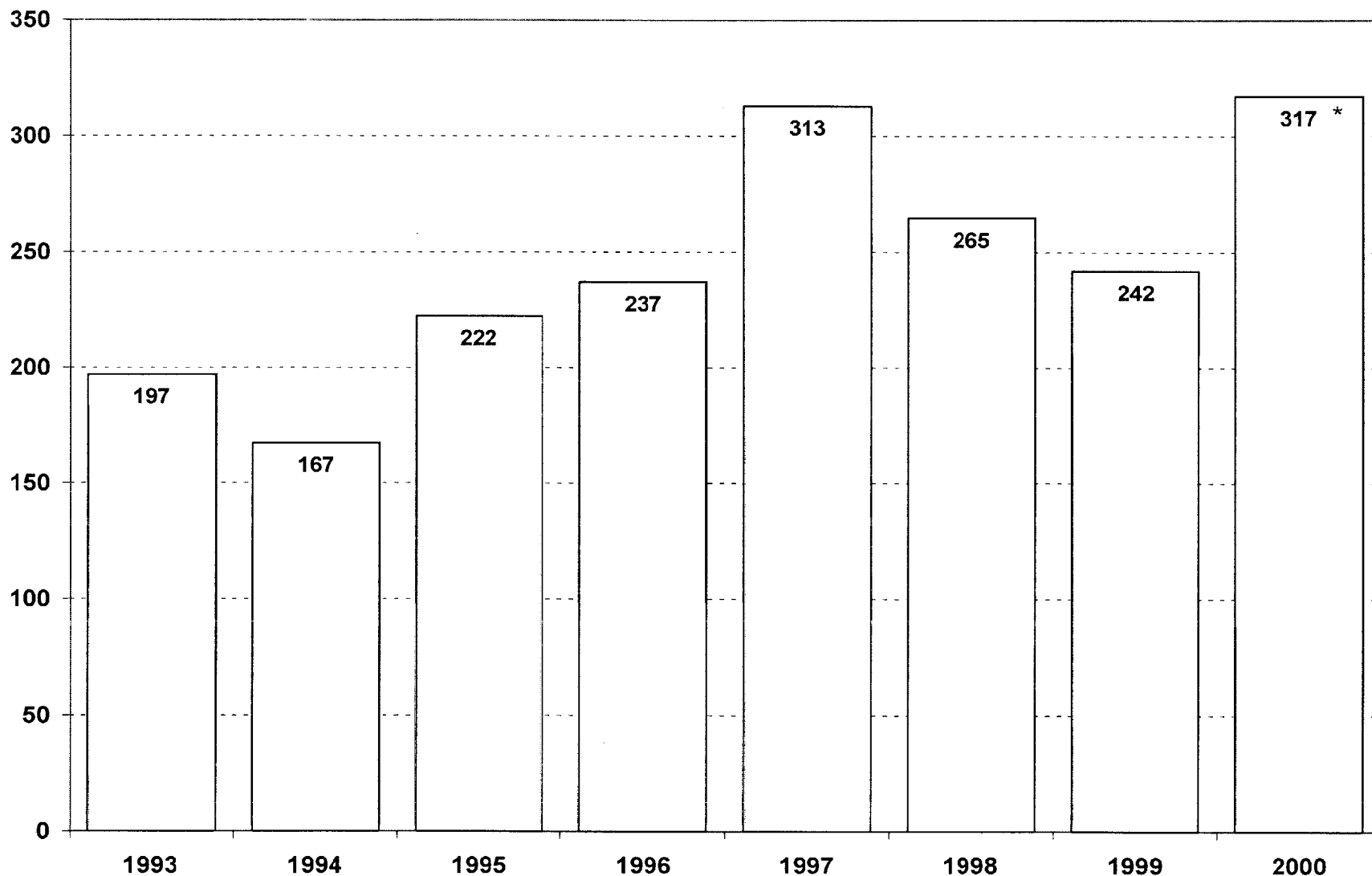
Approvals and Tentative Approvals

By Month





Approvals and Tentative Approvals

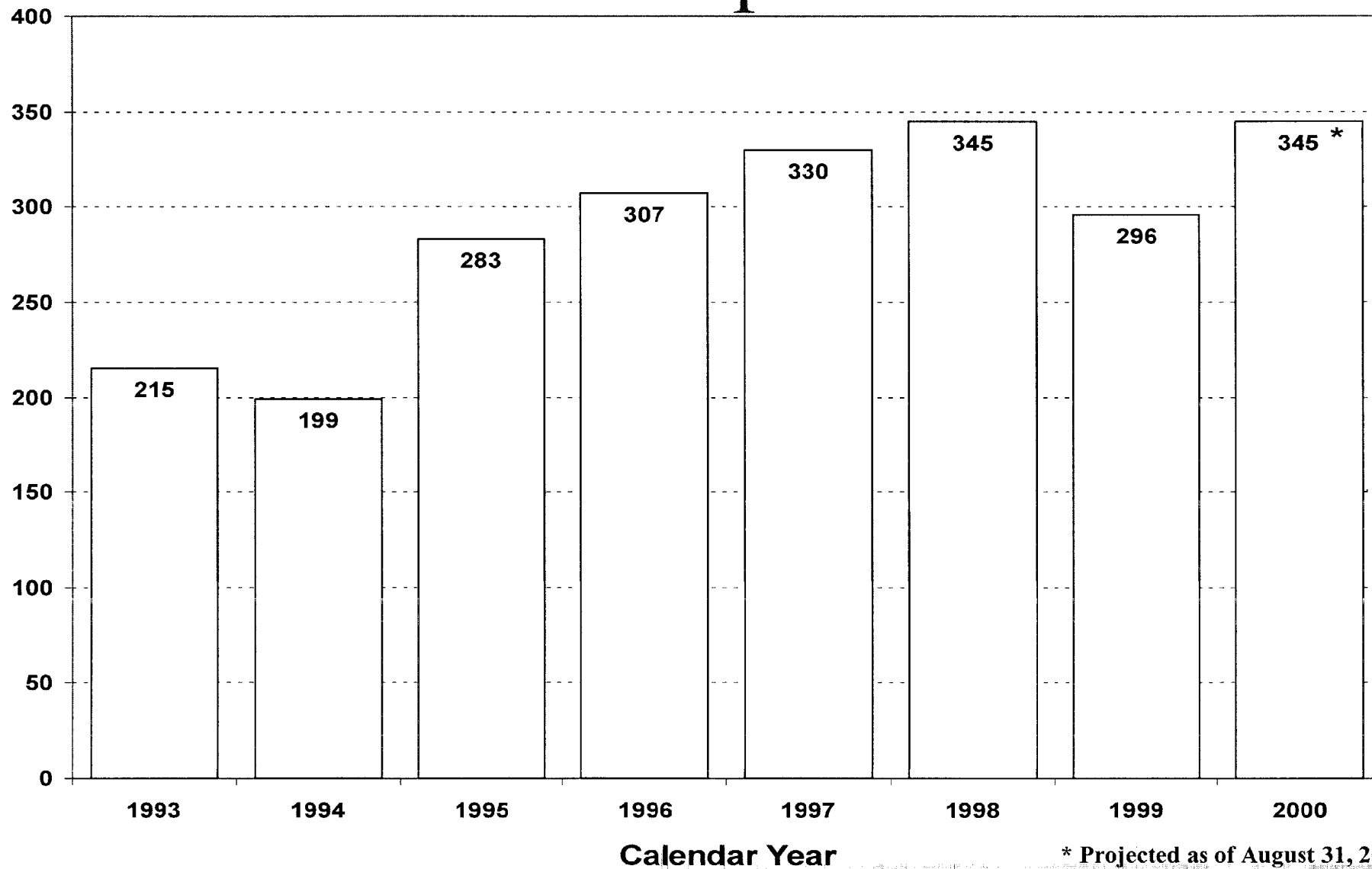


* Projected as of August 31, 2000

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Receipts

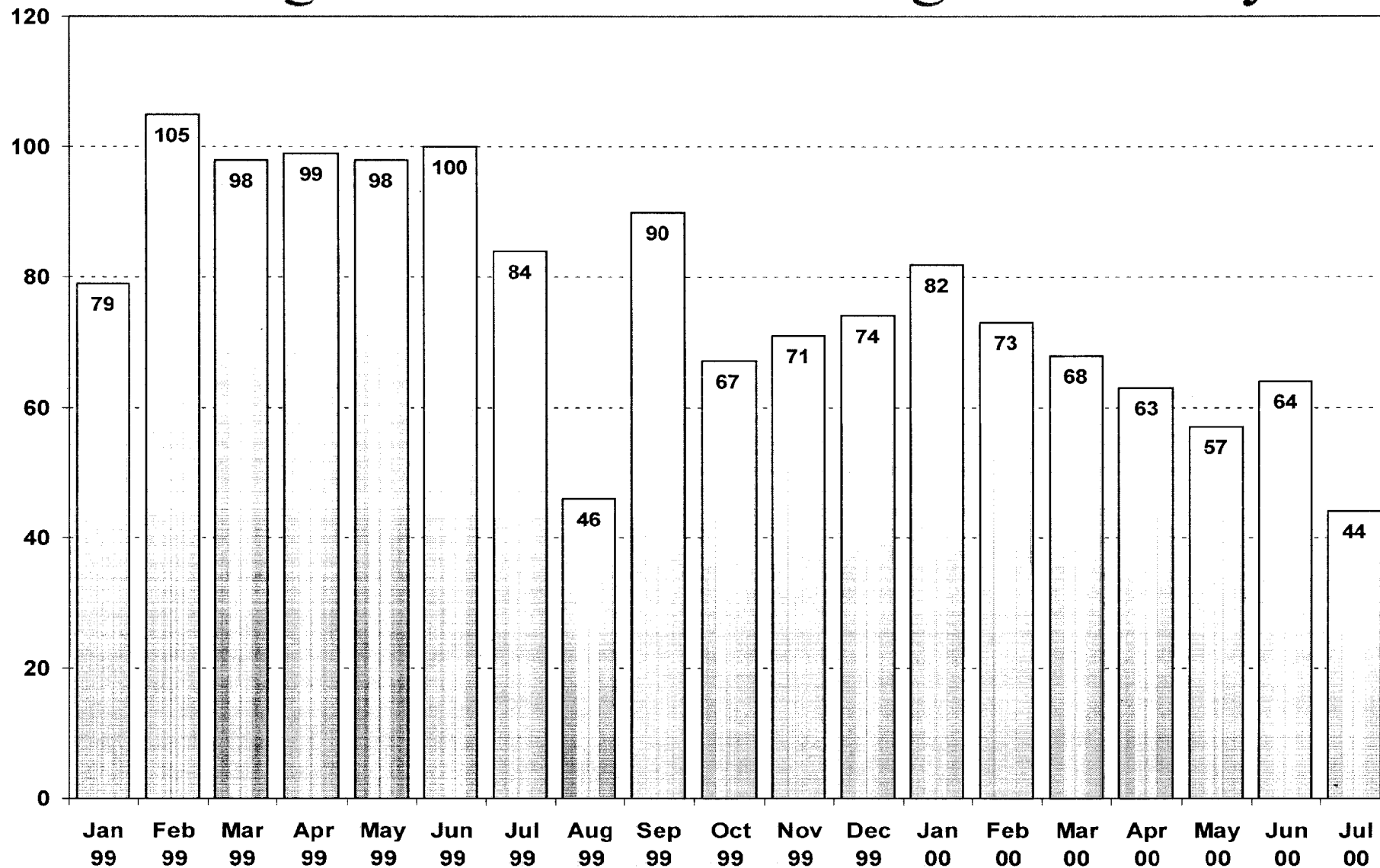


* Projected as of August 31, 2000

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Original ANDAs Pending > 180 Days



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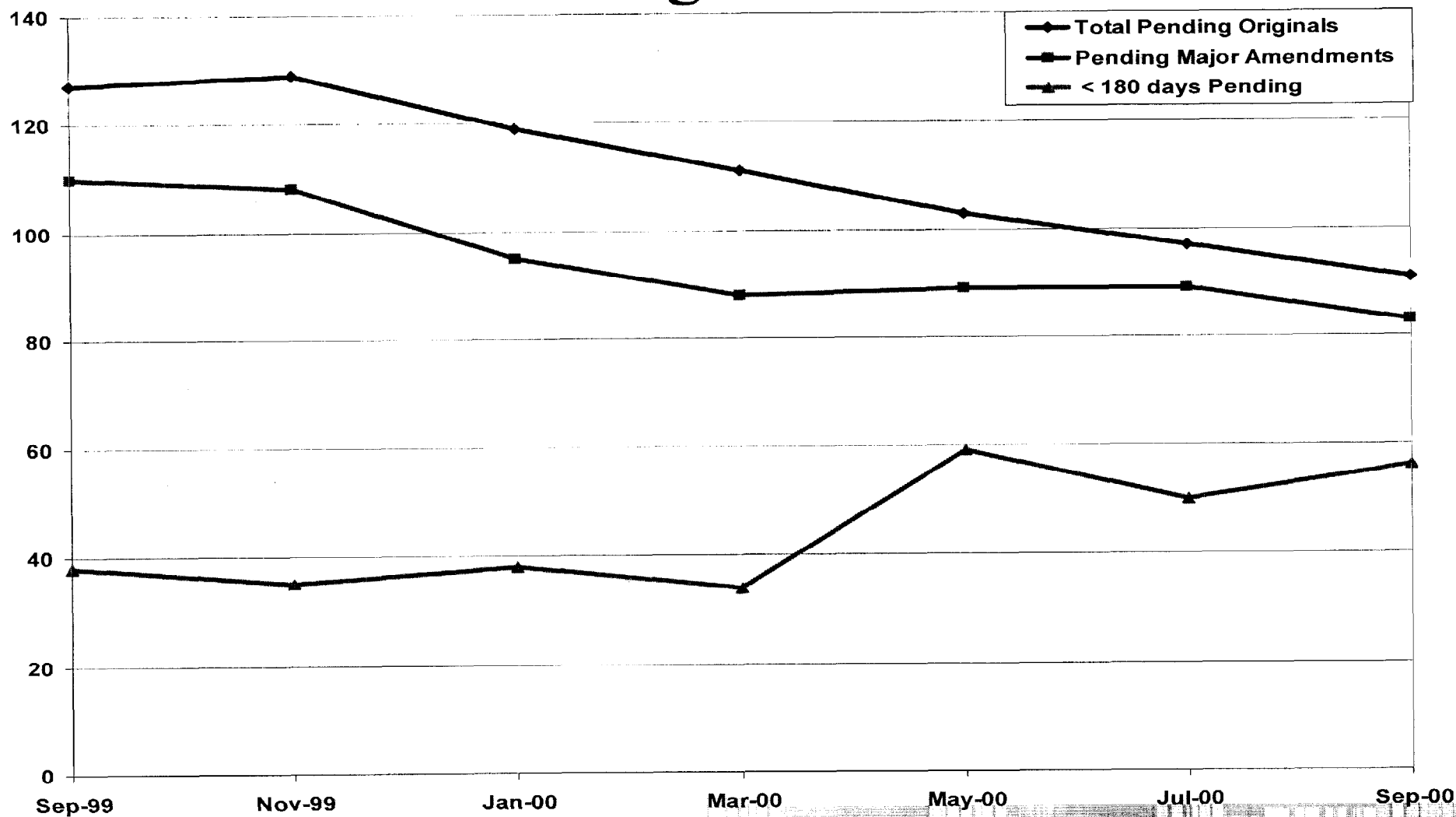
Staffing Update

- Hired in last 12 Months 13
- Projected Hires 9

-	Chemists	6
-	Other	3



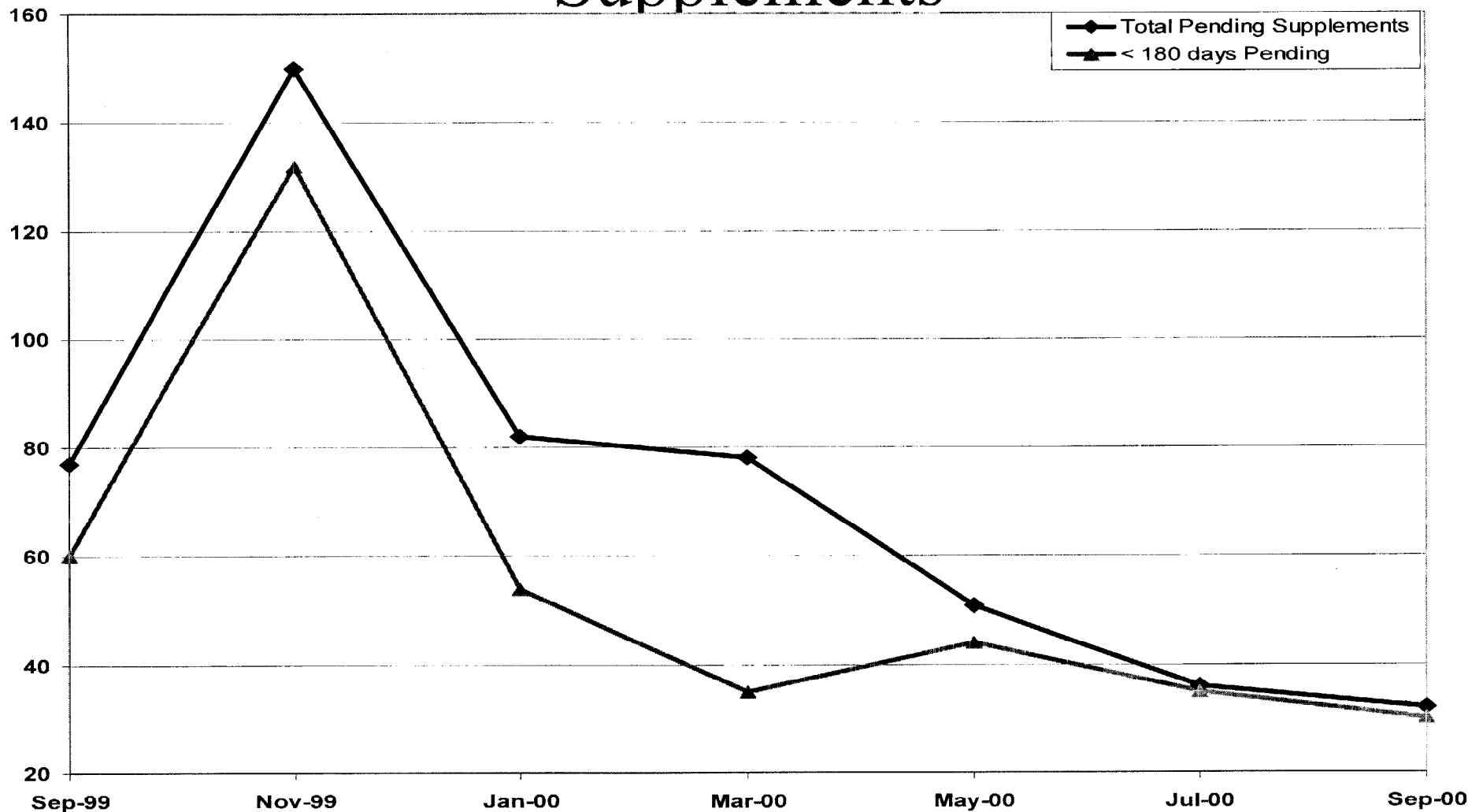
Microbiology Productivity Originals



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Microbiology Productivity Supplements





OGD Director Search



Process Assessment

- Background - "More Work Than Workers"
- Strength of Overall Process
- Suggestions for "Fine Tuning" Overall Process:
 - A. Pre-staging of Chemistry Review
 - B. Decrease "Day to Letter Out"
 - C. Post Routine ANDA Weaknesses on the Web Site



Process Assessment Continued

D. Reviewer Level Committee to Support Professional Morale

- ◆ Functioning Education Committee
- ◆ Plant Orientation Visits
 - Abbott Labs
 - Mylan Pharmaceuticals
 - Teva Pharmaceuticals
- ◆ "Brown Bag" Lunches
- ◆ Video Conferencing



Special Information Technology Expenditures

- Hardware Upgrades for Staff
- Software to Support Review
- Maintenance Support on Inactive Ingredients Database
- Electronic Document Check-In
- Consulting Services for Elec. Subm.



Special Information Technology Expenditures

- Electronic Document Room for ANDAs
- Video Conferencing in MPN2
- COMIS Analyst/Programmer Support
Services

M E M O R A N D U M

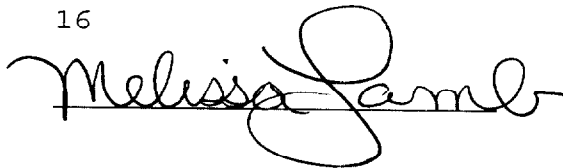
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

6621 '00 OCT 11 P1:44

Date: October 21, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Current Regulatory and Legislative Issues for API
Manufactures

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Office of Generic Drugs: Life After New
Leadership
Presented for: RAPS 2000 Annual Conference & Exhibition
Date Presented: October 2, 2000
Presented by: Gary Buehler
Number of Pages: 16



Attachment

90S-0308

M690



Office of Generic Drugs: Life After New Leadership

**RAPS 2000 Annual Conference
& Exhibition**

**October 2, 2000
Washington, DC**

**Gary Buehler, Acting Director
Office of Generic Drugs**

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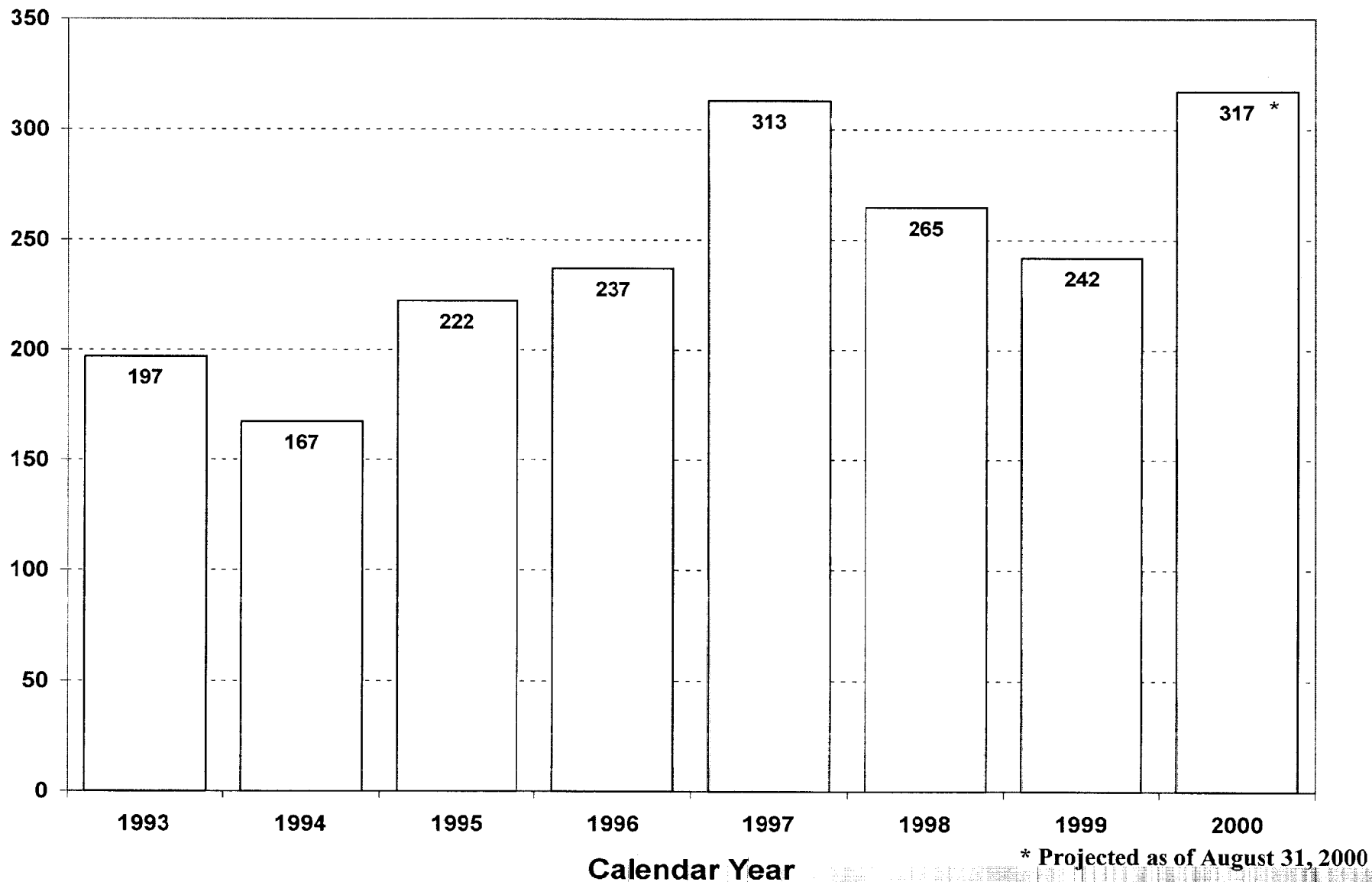


Topics

- Productivity
- Issues
- Look to the Future



Approvals and Tentative Approvals

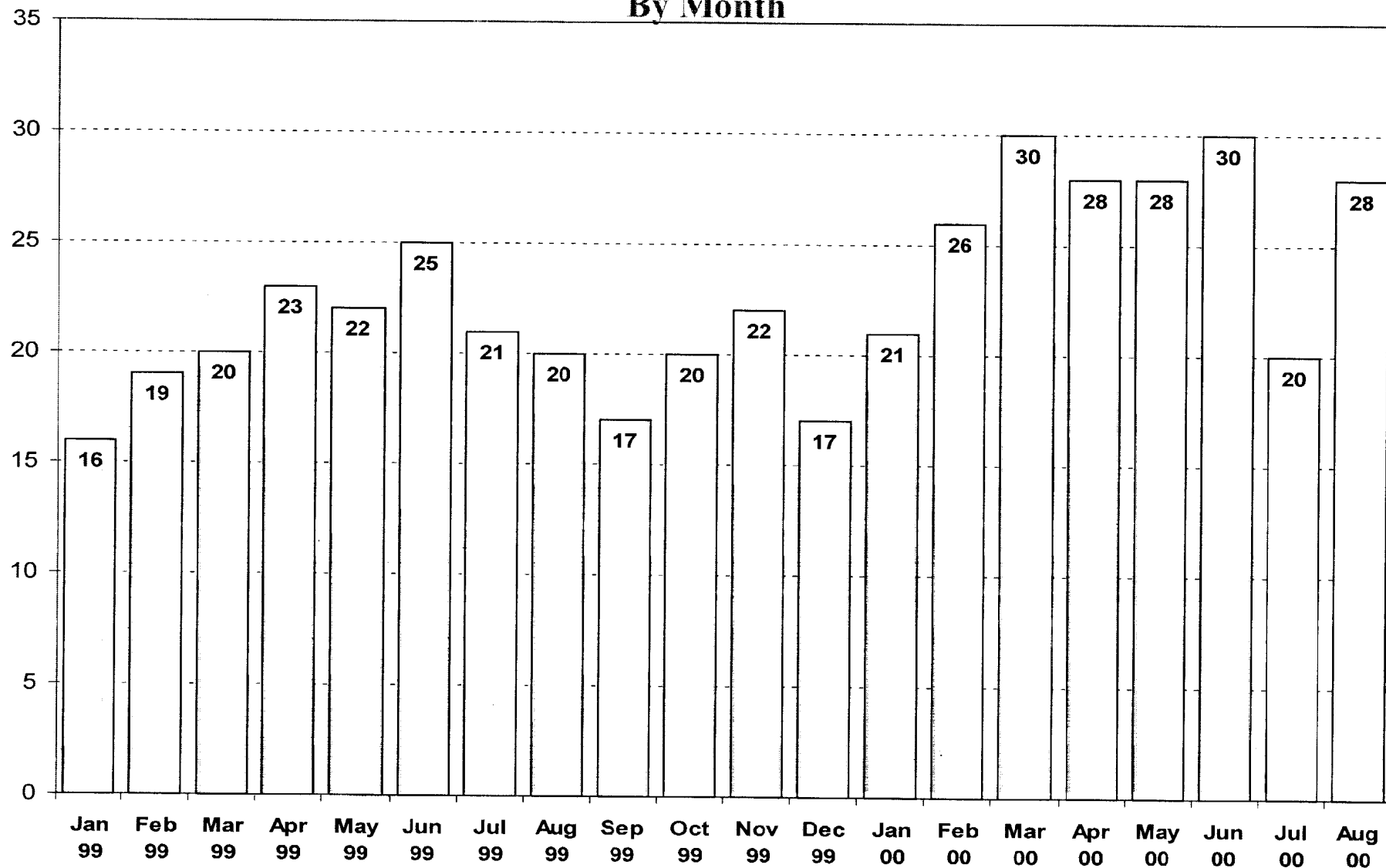


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Approvals and Tentative Approvals

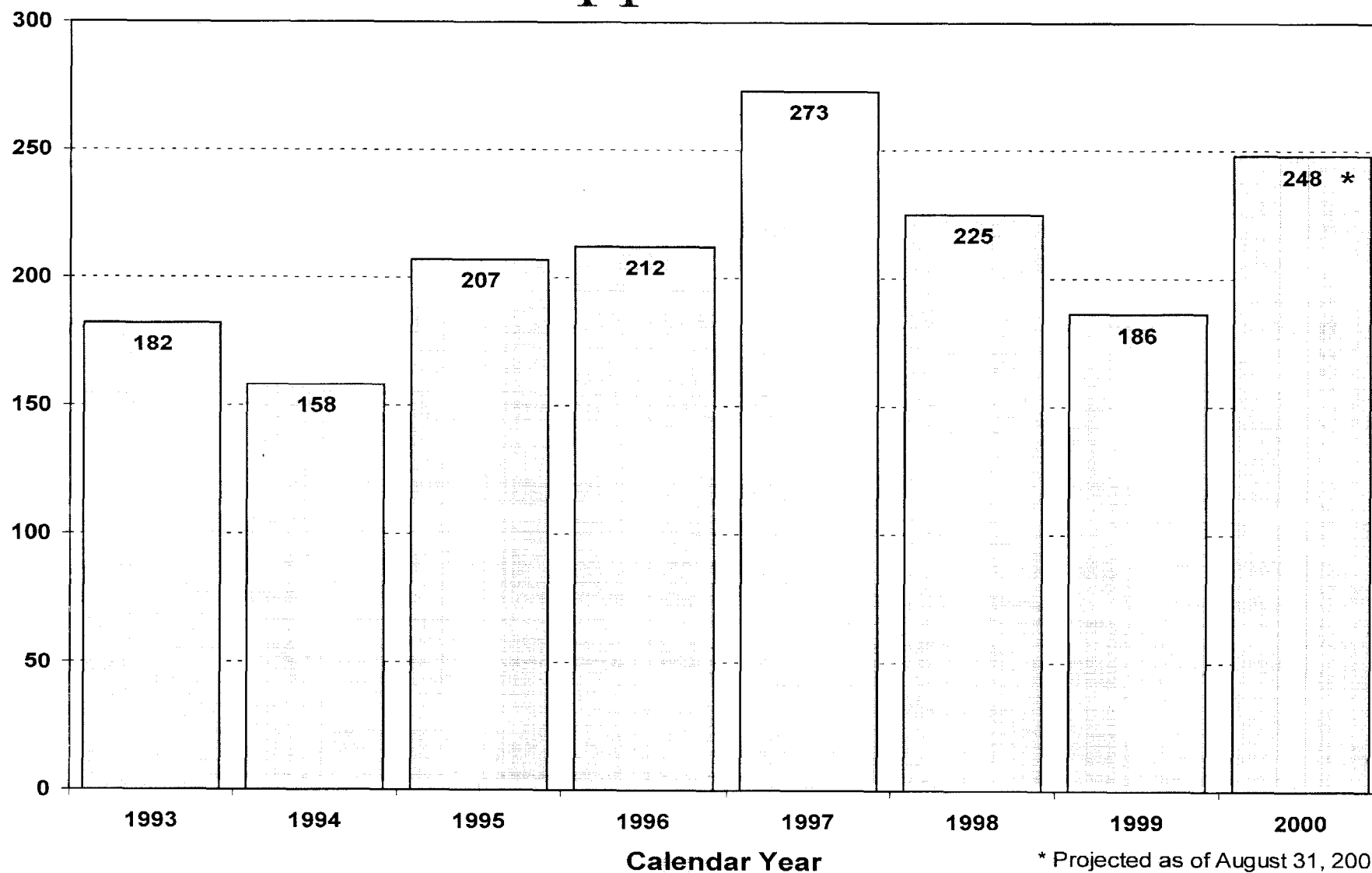
By Month



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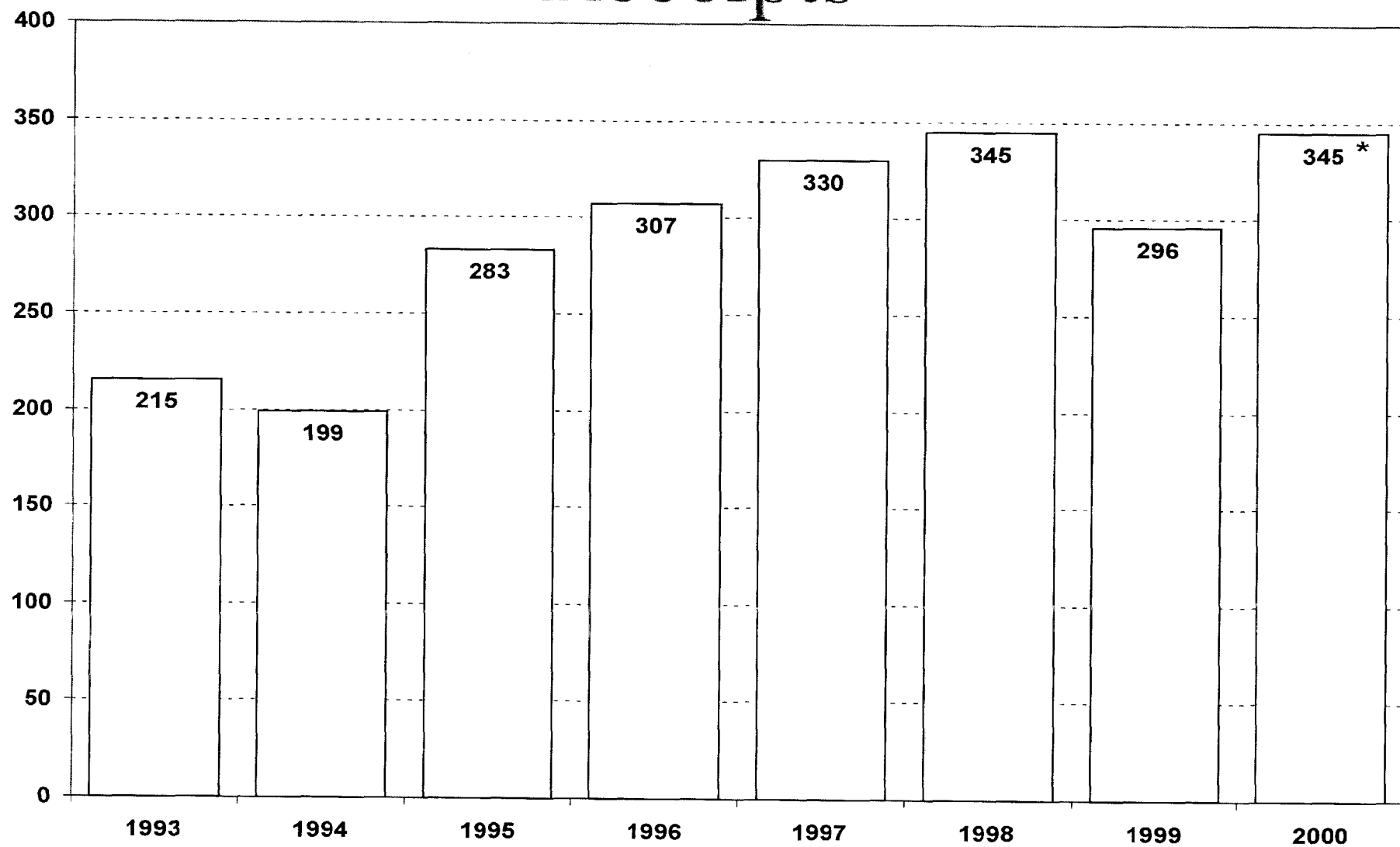
Approvals



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Receipts



Calendar Year

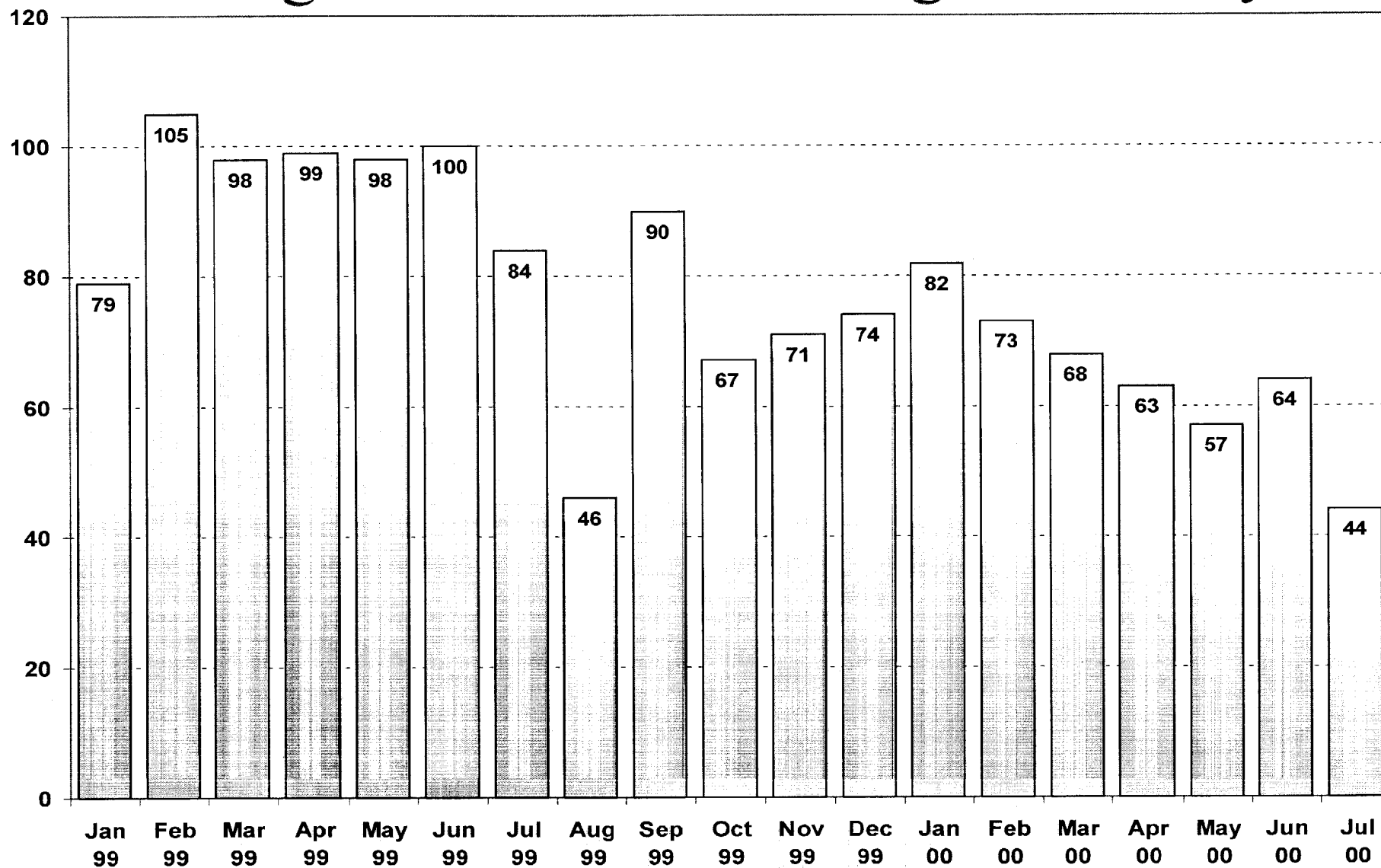
* Projected as of August 31, 2000

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Original ANDAs Pending > 180 Days



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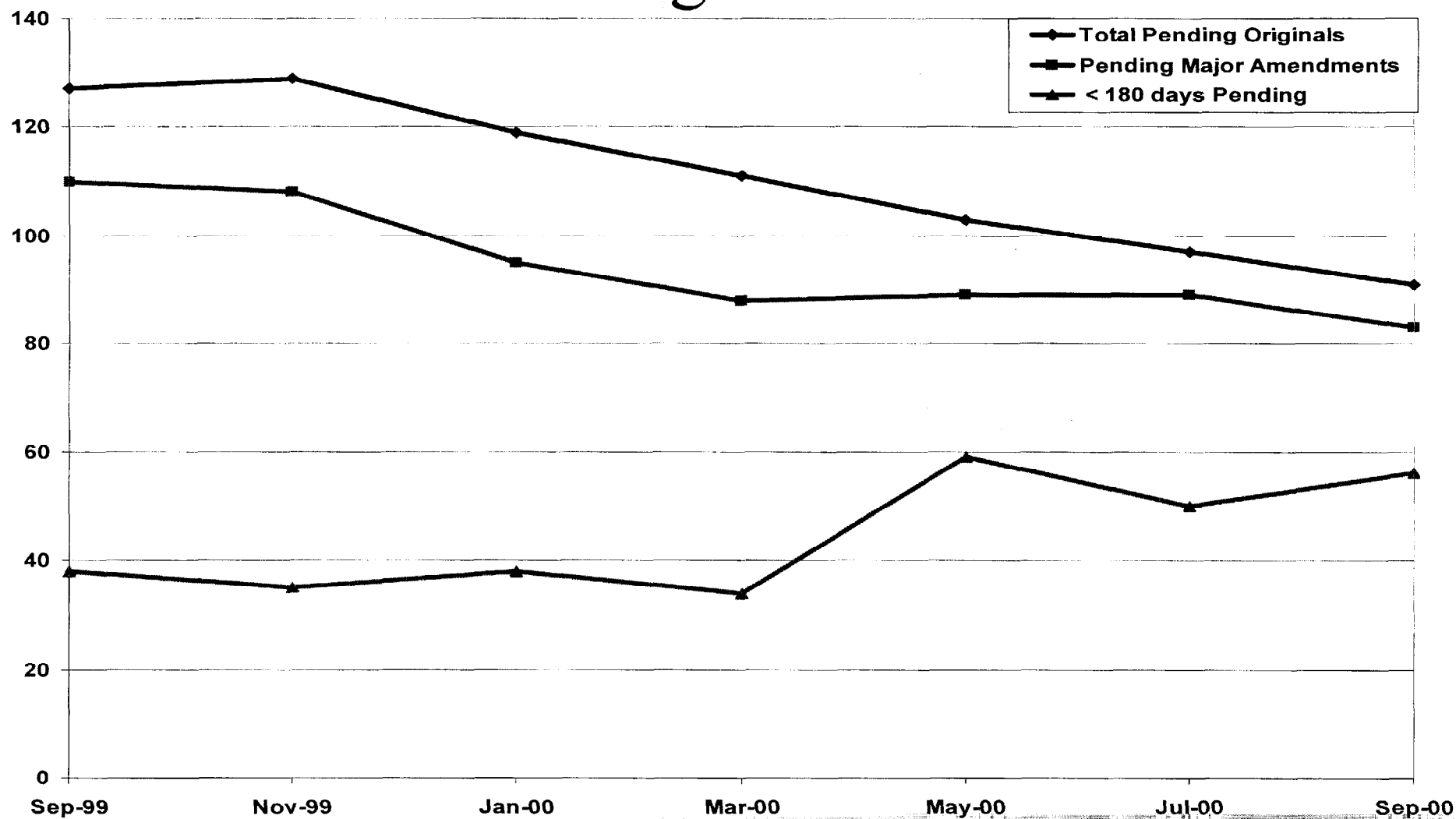
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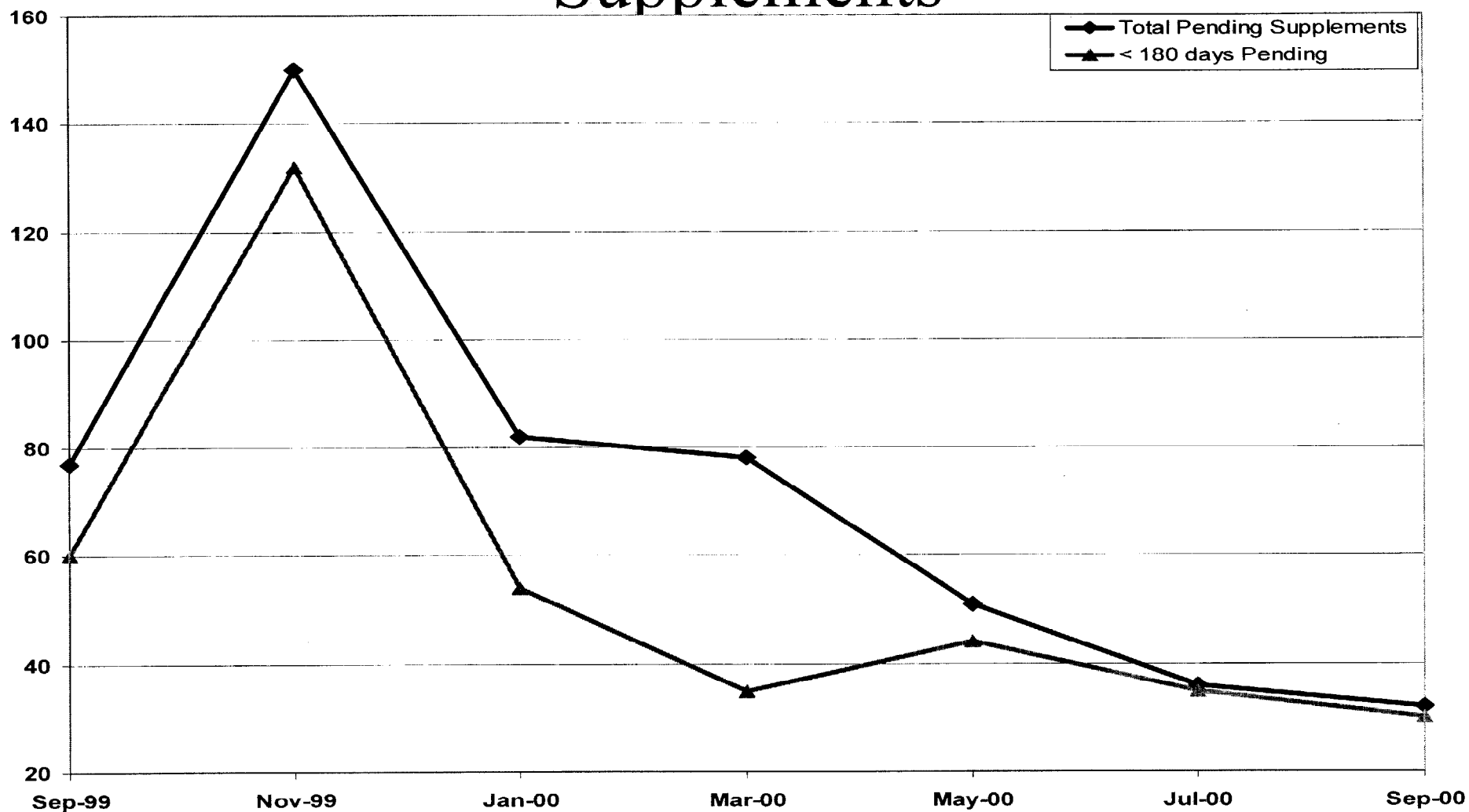


Microbiology Productivity Originals





Microbiology Productivity Supplements





Issues

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Inactive Ingredient Guide(IIG) Update

- 1996 Version Outdated and Inadequate
- Data in 1996 IIG are Not Compatible with Post-1996 Data
- Personnel & Money are being Allocated
- > 6000 Applications must be reviewed
- Completion - Summer 2001 (??)
- Should Result in an Accurate, User-Friendly and Updateable Document

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Methods Validation

Proposing to Drop the 30-Day Waiting Period for Methods Validation



180 Day Exclusivity Proposed Rule (August 1999)

Summary of Industry Comments Received

	Triggering Period	Shared Exclusivity	Only First Applicant Eligible	Rolling Exclusivity	Content Based Standard for Exclusivity (Reformulation and Bio Study)	Patent Based Exclusivity	Product Based Exclusivity	Period During Which Exclusivity Can be Transferred	Effective Date of Implementation	Court Decision on Single Patent	Multiple Strength Exclusivity
A. Engelberg, Esq.	O			F							
Agvar	F								O		
Andrx	O			F	O					O	F
BMS	O					F	O				
FTC	F		F	O							
GPIA	O	O	O	F	O			O	O	O	
Hyman, Phelps & McNamara									O		
J. Rubin, Esq.				F	O						
Lilly	O										
McKenna & Cuneo (N P A)	O			F	O				O		
N A P M	F							O			
Perrigo	F	O	F	O				O	O	O	
Ph R M A	O					F	O				
P L M A	F	O	F	O		O	F	O			
Purepac	O	F	O	F	F	O	F	O			
Schein	F		O	F				O	O	O	
TEVA	O		F	O	O		F	F	O	O	F
Upsher Smith	O			F		F		O			F
Winston & Strawn (Barr)	O	O	O	F	O			O	O	O	

F = Favor Proposed Regulations, O = Oppose Proposed Regulations



Look to the Future

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OGD Director Search